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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

JUN - 9 2000

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

James R. Weersing
President and Chief Executive Officer
IOMED, Inc.
3385 West 1820 South
Salt Lake City, Utah 84104

Re: Iontophoretic Drug Delivery Systems and Electrodes

Dear Mr. Weersing:

The Food and Drug Administration (FDA) has reviewed promotional materials, including information from your website at http://www.iomed.com, for the Iontophoretic Drug Delivery Systems, including the NUMBY STUFF System, the Phoresor Systems (including the Phoresor, Phoresor II Auto Model PM850, and the Phoresor II Model PM900 dose controller), and GelSponge, IOGEL and TransQ drug delivery electrodes. These products are manufactured by IOMED, Inc., and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

These devices have been cleared under section 510(k) of the Act. IOMED's iontophoresis drug delivery systems are indicated for the administration of soluble salts and other drugs into the body for medical purposes as an alternative to hypodermic injection in situations when it is advisable to avoid the pain that may accompany needle insertion and drug injection; when it is advisable to minimize the infiltration of carrier fluids; to avoid the damage caused by needle insertion when tissue is traumatized, and for production of local dermal anesthesia using Iontocaine. IOMED has received NDA clearance from the Center for Drug Evaluation and Research (CDER) for Iontocaine, but has not received NDA clearance for the use of its iontophoresis drug delivery systems with specific drugs other than Iontocaine, or for the use in the treatment of specific medical conditions.

The information we reviewed includes: (1) promotional materials submitted by your firm to our office, as well as the IOMED website and (2) a promotional flyer that pertained to a conference entitled "Drug Delivery Systems 2000" which was scheduled to have taken place January 24-26, 2000 in San Francisco.

In a letter to our office on October 18, 1999, IOMED indicated that their firm is the only company to have a drug (Iontocaine) approved by the FDA, via an NDA, for iontophoretic delivery, and that the firm is in Phase III clinicals with dexamethasone, which will lead to another NDA to be filed. IOMED also indicated that, after reading the Empi warning letter, promotional materials and labeling were reviewed and potential discrepancies were addressed. We note that changes were indeed made to your website and promotional materials; however, we still note continued references to dexamethasone and specific medical conditions.

Your website contains claims related to the delivery of dexamethasone, the treatment of specific medical conditions, and anti-inflammatory treatments. There are discussions of current projects, development and investigational uses of the iontophoresis devices, including a prototype system for patient self-administration of dexamethasone, iontophoretic administration of hydromorphone for pain control (specifically noted on the website as "Investigational Use Only"), and the iontophoretic administration of dexamethasone for the treatment of acute local inflammation such as epicondylitis (tennis and golfers'elbow) and other non-specific, acute, soft-tissue inflammatory conditions. Other examples are noted below.

Your iontophoresis drug delivery systems have not yet been cleared for delivery of dexamethasone. On your website, under the "Products," subheading "Silver-Silver Chloride (SSC)," there is a reference at the bottom citing an article called "Iontophoresis of Dexamethasone: Laboratory Studies." The website heading "Corporate Profile," subtitle "Marketed Products," states that "IOMED currently markets iontophoretic drug delivery systems for the delivery of dexamethasone...," and "Dexamethasone is a potent, effective corticosteroid used to treat local inflammatory conditions such as tendonitis. Presently, dexamethasone is used only as a second or third line therapy....The Company's system, currently marketed under 510(k) clearance, offers patients the benefits of the most effective anti-inflammatory drug available...The Company believes that with NDA approval, IontoDex, a variation of this product in a patient friendly, second-generation iontophoretic delivery system could effectively compete in the...NSAID...and COX-II Inhibitor market." There is a link at the "Corporate Profile" heading to www.lhai.com, Lippert/Heilshorn & Associates, Inc. At this website's IOMED client page, it states "The initial product, a system to deliver dexamethasone sodium phosphate, a corticosteriod (sic) to treat acute local inflammation, has been used by physical therapists and athletic trainers in over 11 million applications for acute tendonitis, bursitis and carpal tunnel syndrome."

Your iontophoresis drug delivery systems have not been cleared for anti-inflammatory treatments. The flyer noted in item #2 above discusses a presentation which was to be given by Mr. Steve L. Hamilton, IOMED's Vice President, Business Development, on "IontoDex Iontophoretic Drug Administration for Acute Local Inflammation." The Numby Stuff brochure (P/N 1240016) submitted by IOMED states "....IOMED's system has been used in...treatments involving painful, local, soft tissue inflammatory conditions." We also advise you that the Phoresor II Auto Model PM850 Instruction Guide (P/N 1920022), page 7 VII.B., states "For anti-inflammatory treatments: use only water soluble medications...".

Your iontophoresis systems have not been cleared for the treatment of specific medical conditions. Press releases on your website (including October 28, 1999, August 13, 1999, August 11, 1999, July 22, 1999, and March 16, 1999) discuss IOMED's drug delivery systems, cleared via the FDA's 510(k) process, have been used to treat local inflammatory conditions such as tennis elbow, joint sprains and strains; and treatable conditions by iontophoresis include acute local inflammatory conditions such as carpal tunnel syndrome, lateral and medial epicondylitis, plantar fasciitis and other musculoskeletal inflammatory conditions. Other statements discuss IOMED's products for treatment of acute local inflammation and the use of IOMED's iontophoretic drug delivery technology to deliver dexamethasone sodium phosphate.

In the various letters to your firm granting substantial equivalence to the Iontophoretic Drug Delivery Systems and Electrodes, including but not limited to those for K896444, K914264, K934335, K954126, K974855, and the most recent clearance (K982668, March 2, 1999), the FDA states (or with similar wording) that "our substantially equivalent decision does not apply to any specific drugs other than Iontocaine that you might label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor may you package drugs with your device prior to FDA having approved the drugs for iontophoretic administration."

We are aware that IOMED, Inc. was formerly called Motion Control, Inc. and that there were 510(k) submissions for the Phoresor PM600 and the Phoresor II PM700 under this firm's name. These devices included labeling indications for the administration of dexamethasone sodium phosphate for acute and subacute bursitis, epicondylitis, and acute nonspecific tenosynovitis. However, subsequent discussions and correspondence between FDA and IOMED noted that prior drug NDA approval for iontophoresis use was required. All of IOMED's 510(k)s since 1978, including the Phoresor II PM700, were subsequently cleared under 510(k) K954126 for modification of the labeling of the Phoresor Drug Delivery System to include the iontophoretic administration of Iontocaine. The substantial equivalence letter also included the requirement for prior drug approval. The Phoresor PM600 was not included in the modified labeling since it was no longer manufactured and sold.

Therefore, it is our belief that IOMED's devices should neither be labeled nor promoted for use with specific drugs (i.e., dexamethasone), nor should you package drugs with your device, prior to FDA having approved the drugs for iontophoretic administration. Iontocaine has only been approved for production of local dermal anesthesia. There have not been any anti-inflammatory drugs approved and labeled for iontophoretic delivery. Therefore, you can not make any claims related to the use of any other specific drug or class of drugs, for use in the Iontophoretic Drug Delivery Systems, unless the drug has been cleared for use in your devices by the FDA.

The FDA has not approved the use of your device for the treatment of specific conditions. Marketing the Iontophoretic Drug Delivery Systems for treatment of the specific conditions listed above, or any other claims for uses which have not been cleared by FDA, and labeling or promoting your device for use with specific drugs, i.e., delivery of anti-inflammatory drugs, without FDA approval of an NDA for such use, causes the device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Iontophoresis Systems are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device. Additionally, the promotion of the iontophoresis devices for use with a specific drug without an approved NDA is prohibited under section 505(a) of the Act.

Additionally, our Office of Device Evaluation (ODE) has reviewed your premarket notifications, and could not find a 510(k) for the Phoresor PM 850. Please provide us with the 510(k) number for this device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Iontophoresis Systems. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Denver District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Denver District Office (HFR-SW200), P.O. Box 25087, 6th and Kipling Streets, Denver, Colorado 80225-0087.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health